

### REMARKS

Claims 1 - 42 and 47 - 60 have been withdrawn from consideration. Claim 43 has been amended. Claim 61 has been added. Claims 43 - 46 and 61 are now pending in this application. Applicants respectfully submit that no new matter has been added. In view of the above amendment and the following remarks, it is respectfully submitted that all of the presently pending claims are allowable.

Claims 43 and 44 stand rejected under 35 U.S.C. § 102 as anticipated by Yoon (U.S. Patent No. 5,797,888).

Amended claim 43 recites a medical device comprising "an elongate catheter including an external surface and at least one internal surface defining an internal lumen that extends longitudinally along at least a portion of the elongate catheter" and "a compound slit extending from a generally hemispherical portion of the external surface to the at least one internal surface and into communication with the internal lumen, *the compound slit being biased toward a closed position and opening in response to a difference between a fluid pressure within the lumen and a fluid pressure outside the catheter.*"

Yoon purports to show a cannula for insertion through an anatomical cavity wall. (See Yoon, Abstract). The cannula 20 has a sleeve 22 with a seal 24 at a distal end thereof which is designed to open when a tool is thrust therethrough. (See id., col. 4, lines 25-30). The seal 24 includes four flaps 28 biased toward a closed position. (See id., col. 4, lines 42-47). The flaps 28 open outwardly only when a pusher 26 or instrument 62 is pushed therethrough. (See id., col. 7, lines 20-37). The valve of Yoon is useful only to prevent fluid from passing therethrough as it seals around the pusher 26 or instrument 62 when such is passed therethrough and seals tight when no instrument extends therethrough. Specifically, Yoon states that the valve 24 "can have any configuration to prevent fluid flow through the cannula prior to the introduction of instruments through the cannula, after the instruments are withdrawn from the cannula and/or

while the instruments are in place.” (*Id.*, col. 9, lines 54-57).

The device of Yoon teaches away from the configuration claimed by the applicants. The applicants have disclosed a catheter that opens in response to a difference between a fluid pressure in the lumen and a fluid pressure external to the catheter. To accomplish the aspiration function, the compound slit is “able to flex into the internal lumen” when the lumen pressure is less than the environmental pressure. The valve 24 in Yoon never opens inwardly and only opens outwardly as a result of being physically pushed by the pusher 26 or the instrument 62. The valve 24 acts to prevent all fluid flow back into the cannula 20.

Thus, it is respectfully submitted that Yoon neither illustrates nor describes a medical device comprising “an elongate catheter including an external surface and at least one internal surface defining an internal lumen that extends longitudinally along at least a portion of the elongate catheter” and “a compound slit extending from a generally hemispherical portion of the external surface to the at least one internal surface and into communication with the internal lumen, *the compound slit being biased toward a closed position and opening in response to a difference between a fluid pressure within the lumen and a fluid pressure outside the catheter,*” as recited in claim 43. It is therefore respectfully submitted that claim 43 is not anticipated by Yoon and that this rejection should be withdrawn.

Because claims 44 - 46 and new claim 47 depend from and, therefore, include all of the limitations of claim 43, it is submitted that these claims are also allowable.

Claim 45 stands rejected as obvious over Yoon in view of Phelps et al. (U.S. Patent No. 6,419,659). The Examiner stated, in support of the rejection, that Yoon shows a device as claimed except for the element of a collar disposed at the distal end of the catheter, but that Phelps discloses a collar 46 disposed adjacent the catheter’s distal-most end. The Examiner further stated that it would have been obvious for one of ordinary skill in the art to combine the above mentioned prior art and that “doing so would provide an attending physician with means

for determining the location of the catheter by magnetic or electromagnetic means (Phelps column 4, lines 30-35)."

It is respectfully submitted that claim 45 is allowable for the same reasons stated above in regard to claims 43 and 44 and that Phelps does not cure the noted defects.

Claim 46 stands rejected as obvious over Yoon in view of Desai (U.S. Patent No. 5,857,464). The Examiner stated, in support of the rejection, that Yoon shows a device as claimed except for the element of a tricuspid flap configuration, but that Desai discloses a valve 40 with three flaps 43. The Examiner further stated that it would have been obvious for one of ordinary skill in the art to combine the above mentioned prior art and that "it would be a simple matter of choosing a design for an end valve from existing designs known in the art, when each design would perform equally well."

It is respectfully submitted that claim 46 is allowable for the same reasons stated above in regard to claims 43 and 44 and Desai fails to cure the above-noted defects.

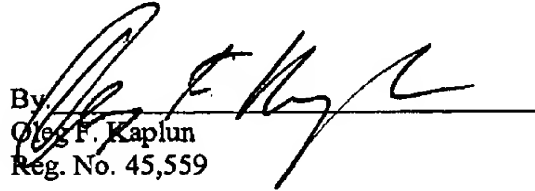
In addition, it is respectfully submitted that new the cited references fail to show or describe any medical device with a compound slit "configured so that, *when the fluid pressure within the lumen exceeds the fluid pressure outside the catheter by a first predetermined amount, flaps of the hemispherical portion formed by the compound slit flex outward away from a longitudinal axis of the catheter to allow fluid within the lumen to exit and, when the fluid pressure outside the catheter exceeds the fluid pressure within the lumen by a second predetermined amount, the flaps flex into the lumen to allow fluid outside the catheter to enter the lumen,*" as recited in new claim 61.

It is therefore respectfully submitted that claim 61 is allowable for these reasons in addition to those stated above in regard to claim 43 from which it depends.

It is therefore respectfully submitted that all of the presently pending claims are allowable. All issues raised by the Examiner having been addressed, an early and favorable action on the merits is earnestly solicited.

Respectfully submitted,

Dated: June 1, 2004

By   
Oleg F. Kaplun  
Reg. No. 45,559

Fay Kaplun & Marcin, LLP  
150 Broadway, Suite 702  
New York, New York 10038  
Tel: (212) 619-6000  
Fax: (212) 619-0276